DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office	DATE(S) OF INSPECTION 8/19/10-8/26/10			
11630 W 80 th St Lonexa, KS 66214-3340 (913) 752 2100	FEI NUMBER 3004354976, 3004404403, 3006481690			
NAME AND TITLE OF INDIMIDUAL TO WHOM REPORT IS ISSUED				
TO: Gary W Bartness, General Manager	STREET ADDRESS			
FIRM NAME Hillandale Farms of Jowa, Inc	19 1/2 West Main			
CITY, STATE AND ZIP CODE New Hampton, IA 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer			
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES (S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN REPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE (S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE. Observations listed below cover inspections of your egg laying farms/plants inspected from 08/19/2010 through 08/26/2010. FEL: 3004354976 - Hillandale Farms of Iowa, Inc, 19 ½ West Main, New Hampton, IA 50659 FEL: 3004404403 - Hillandale Iowa II, LLP, 13706 230th St, West Union, IA 52175 (referred to as West Union) FEL: 3006481690 - Hillandale Farms, LLC, 13998 140th St, Alden, IA 50006 (referred to as Alden) 1. You did not maintain documentation that the 19 week old pullets in house 4 at the Alden facility were "SE monitored" or				
were raised under "SE monitored" conditions, including environmental testing records for pullets. 2. The written SE prevention plan was not fully implemented and followed.				
Specifically, a) Your document "Hillandale II LLP Bio-security Plan" (referenced in your Hillandale II LLP Salmonella Enteritidis Prevention Plan) created 5/1/10 states on p. 7 under the section entitled, "*** you will "*** (b) (4) ***" You failed to follow your plan as evidenced by the following observations on 8/23/10:				
 West Union House 1 — There were 3 unsealed rodent holes observed along east wall. 				
 West Union House 4 - There were 16 unsealed rodent holes along row 1. Two live rodents were observed entering into 2 of the rodent holes. 				
 West Union House 5 There were approximately 20 unsealed rodent holes on south wall along row 7. A rodent was observed running into one of the rodent holes. West Union House 8 There were 26 unsealed rodent holes on the south wall of the house. In addition, there were 5 unsealed rodent holes on the east side of the house. 				
SEE 75 A	(EE(S) NAME AND TITLE (Prim or Type) P. Moody, Investigator R. Lambart, Investigator ny. Fishen, Invest, gator a. M. McClure, Invest, sator o. A. Ramifez, Invest, sator T. Hall c. Invest, gator			

DISTRICT OFFICE ADDRESS AND PHONE	NUMBER		DATE(S) OF INSPECTIO 8/19/10-8/26/10	N
FDA Kansas City District Office 11630 W 80 th St			8/19/10-8/20/10 FEI NUMBER	
Lenexa, KS 66214-3340	(913) 752 2100		3004354976, 30044	04403, 30064
NAME AND TITLE OF INDIVIDUAL TO WHO	M REPORT IS ISSUED			
TO: Gary V Barta	ess, General Mana	900		
FIRM NAME		STREET AOU 19 1/2 We		,
Hillandale Farms of Iowa, Inc			TABLISHMENT INSPECTED	
New Hampton, IA 50659		Egg Manu		
In addition the section entitled, "**		李東京29 ((東東東	also found on p. 7 states t	he following:
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	b) (4)	***	(b) (4)	
(b) (4)	***". You faile	ed to follow your pla	in as evidenced by the fol	lowing observ
on 8/23/10:				
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There was an approximate 2 inch g				
end approximately 5x3 inches.	-P 211 40011 1100 01 1110 00			
• West Union House 5 - There was	an approximate 1.5 inch	gap in east door.		
• West Union House 6 - There was	an approximate 6 inch g		the east door and an app	roximate 3 in
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• West Union House 6 – There was the damaged door on the east side of	an approximate 6 inch gof the building.	gap on the outside of		roximate 3 in
• West Union House 6 – There was the damaged door on the east side of	an approximate 6 inch gof the building.	gap on the outside of		roximate 3 in
• West Union House 6 - There was	an approximate 6 inch gof the building. an approximate 2 inch g	ap on the outside of	ce door.	roximate 3 in
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED				
TO: Gary W Bortness, General Manage	V			
FIRM NAME Hillandale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main			
CITY, STATE AND 2IP CODE New Hampton, TA 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer			
• Alden House 7 – Light was obscrved coming in around the perimeter of the west door due to inadequate seal. No seal was on the north rear manure door.				
 Alden House 8 – Holes were observed in the walls on the protruding into the manure pit. 	he north side of the building, approximately 1 foot by 2 feet,			
	rved on the manure pit door at the west end of the house. Two holes in diameter, on the south side of the building underneath the rapproximately 2 inches in diameter.			
Prevention Plan) created 5/1/10 states under (b) (4) (b) (4)	(4) " on page 12, "** (b) (4) (c) (4) (d) (d) (e) (d) (e) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f			
follow your plan as evidenced by the following observati				
 Alden House 2 – Standing water approximately ¼ inch foot bath was located inside the building. 	deep was observed on the floor adjacent to the manure pit where the			
 Alden House 8 – Liquid manure was observed leaking is water line leak occurred several weeks ago causing the m 	into the east section of the first floor. Plant manager reported that a nanure pit to flood.			
d) Your document "Hillandale II, LLP Bio-security Plan" Prevention Plan) created 5/1/10 states under " (b) (4) (b) (4)	(4) on page 12, "*** (b) (4) (c) You failed to			
follow your plan as evidenced by the following observation				
 West Union House 7 - Liquid manure was observed stre manure pit. Plant manager reported a water leak had occur 	eaming out of an approximate 6 inch gap of the east door of the urred.			
e) Your document "Hillandale Iowa LLC Bio-security Plantage Provention Plant ordated 5/1/10 states on page 8, "	an" (referenced in your Hillandale Iowa LLC Salmonella Enteritidis (b) (4) (b) (4)			
	ur plan as evidenced by the following observation on 8/20/10:			
• Alden House 7 - Weeds, approximately 12 inches tall, v	were observed growing along the exterior wall around the entire house.			
SEE REVERSE OF THIS	EMPLOYEE(S) NAME AND TITLE (Print or Type) office B. Moody, Investigator Tisch C. Lambord. Investigator Commeny. Fisher Involugator Morrison M. Miclory Investigator Office Comments of Comments			
PAGE MAN TO THE	Continenty Fisher, Invotigator 8/26/10 Michards Ar Rominti Investigator Broad T. Wall Town Strator			

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FIRM NAME Hillandale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main			
CITY, STATE AND ZIP CODE New Hamoton, TA, 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer			

- 3. You failed to take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. This is evidenced by the following observations on 8/23/10:
- West Union House 7 Approximately 35 un-caged hens were tracking manure from the manure pit into the upper level of the caged hen house area.
- West Union House 4 Approximately 14 un-caged hens were tracking manure from the manure pit into the upper level of the caged hen house area.
- 4. All required records did not include the location of the farm and the signature or initials of the person who performed the operation.

Specifically,

- The "Fly Monitoring Form" for the West Union site (Houses 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 8/6/10, 8/13/10, and 8/20/10 did not include the specific farm location of the fly monitoring and the name or initials of the person who performed the inspection.
- The "Rodent Monitoring Form" for the West Union site (Houses 1, 2, 3, 4, 5, 6, 7, 8, and 9) performed on the dates 7/12/10, 7/19/10, 8/2/10, and 8/23/10 did not include the specific farm location of the rodent monitoring and the name or initials of the person who performed the inspection.
- The "Moving Tape Fly Count" for the Alden site (Houses 1, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 7/29/10, 8/12/10, and 8/19/10 did not include the specific farm of the houses inspected.
- The "Post B Gone" rodent activity logs for the Alden site (Houses 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 7/22/10, 7/29/10, 8/5/10 and 8/19/10 did not include the specific location of the farm inspected and did not always include the name or initials of the person who performed the inspection.
- 5. Your written SE plan titled "Hillandale Iowa LLC Salmonella Enteritidis Prevention Plan" and "Hillandale II LLP Salmonella Enteritidis Prevention Plan" did not include the signature of your plan administrator.
- 6. Samples collected during the course of this inspection and tested by a FDA laboratory, revealed the following positive analytical test results: Spent water from egg wash station from Plant 5, sampled on 8/19/2010, tested positive for Salmonella enteriditis.

SEE REVERSE OF THIS PAGE EMPLOYEEIS) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (PHINI OF TYPE)
JEffrey B Moody, Investigator
Joseph L. Lambert, Investigator
COUMANY, Fisher, Investigator
Monio M. McClure, Investigator
Gerando A. Romiree, Investigator
Gerando A. Romiree, Investigator
Lambert Holl Investigator

DATE ISSUED

8/26/10